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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No.

INVENTOR(S)					
Given Name (first and middle (if any))		Family Name or Surname		Residence (City and either State or Foreign Country)	
Oren		Gavriely		Haifa, Israel	
<input type="checkbox"/> Additional inventors are being named on the _____ separately numbered sheets attached hereto					
TITLE OF THE INVENTION (500 characters max)					
INTRA AIRWAY VENTILATION					
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ENCLOSED APPLICATION PARTS (check all that apply)					
<input checked="" type="checkbox"/> Specification Number of Pages		13		<input type="checkbox"/> CD(s), Number	
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<input type="checkbox"/> Application Data Sheet. See 37 CFR 1.76					
METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT					
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.				FILING FEE AMOUNT (\$)	
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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.					
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Respectfully submitted,

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Oren Gavriely

Date 10/11/02

TYPED or PRINTED NAME OREN GAVRIELY

TELEPHONE 011-972-48242369

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Docket Number

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

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60/425294

While there are many models of ventilators with a variety of features and controls, all IPPV systems are only capable of ventilating the whole lung en bloc, or, at the most ventilating the two lungs with a special, two lumens ETT, using to ventilators. Current technology does not allow ventilation of lobes or segments of the lung individually, despite the substantial inhomogeneity of the disease processes encountered in most lung diseases.

Included here by reference are German Patent 2055049 dated December 16th, 1971; the corresponding Austrian patent 302520 of October 25th, 1972 and a corresponding Canadian Patent. Also included here by reference is US Patent 5,265,593 dated November 30th, 1993 titled "Balloon tipped catheter ventilation system and method for using same having rhythmically inflated and deflated balloon." They all describe an endotracheal tube equipped with a cuff balloon that is connected via an accessory channel to an actuating apparatus that rhythmically inflates the cuff, while a steady flow of air or oxygen is blown through the main lumen of the tube. When the cuff is inflated inside the patient's trachea it occludes the exit of air around the tube and the lungs inflate. When the cuff is deflated, the lungs deflate with gas exiting around the tube, while gas is still flowing into the trachea through the tube's main channel. The lack of control over intra thoracic pressure leading to risk of lung hyperinflation and pneumothorax are major concerns with this method. The invention disclosed herewith describes an improved intra-tracheal ventilation method and tube that overcomes the deficiencies of the previous method.

Description of the present invention

The present invention discloses an intra-tracheal ventilation apparatus and a method of using it. It consists of a thin tube whose distal end is inserted into the patient's trachea. The distal end of the tube is surrounded by a collapsible elastic cuff or balloon whose inner volume is connected to the channel of the tube via one or a plurality of side holes in the wall of the tube. The proximal end of the tube is connected to an intermittent gas delivery system that blows pulses of compressed gas at a specified flow and frequency into the lumen of the tube. When gas such as air or an oxygen mixture is blown into the tube the cuff first inflates and expands to a volume that is sufficient to occlude the airway

in which it resides. Additional air then blown into the tube exits through its distal end or through small fenestrations in the distal portion of the wall of the cuff or through both. This gas can now inflate the lung or lung portions whose main airway is occluded by the inflated balloon. When gas flow into the tube stops at the end of each pulse, the pressure inside the tube's lumen immediately falls and the cuff deflates through the hole(s) connecting its inner volume to the tube's lumen and/or through the fenestrations due to its elastic recoil. Deflating the cuff opens a space around it for exhaled gas to emerge from the lungs or lung portion. In its most basic configuration (Figure 1a) the deflation of the balloon cuff is induced by the elastic recoil of the balloon cuff material, constructed from an elastomer thin membrane such as silicone that can expand and relax thousands of times without changing its elastic properties. Alternatively, applying a suction negative pressure to the tube, thereby actively collapsing the balloon may enhance the balloon cuff deflation.

Major differences from existing art

Major differences are noted between the new method and apparatus disclosed here and the existing and previously described art:

1. The balloon cuff inflation is directly via the tube's (only) lumen and not through a secondary channel extending along the length of the tube as in conventional IPPV endotracheal tubes and as disclosed in previous intermittent cuff inflation tube patents referred to above.
2. The balloon cuff deflation is through the connecting hole(s) between the cuff's inner cavity and the tube's lumen and/or the small fenestrations through its wall and not via the secondary channel that extends along the length of the tube.
3. In a preferred embodiment, the ventilation of the lung is through a plurality of small fenestrations in the balloon cuff wall facing the lung interior and not as a jet projecting from the tip of the catheter.

These differences pose advantages over the existing art as follows:

1. **Narrower tube and tube wall.** Since there is no need to pass a secondary channel along the length of the tube to inflate and deflate the balloon cuff. This feature makes insertion of the tube easier, facilitates insertion of multiple tubes into a plurality of lung segments, and clears a larger portion of the inner cross section of the airway for easy exhalation flow.
2. **The inflation of the balloon is instantaneous and always in full synchronization with the delivery of gas into the lung.**
3. **The deflation of the balloon cuff is quick, immediately after the end of the gas flow pulse.** This feature prevents the risk of occlusion of the secondary channel causing gas trapping inside the balloon and leading to a risk of impeded lung emptying, build-up of intrathoracic pressure with catastrophic consequences such as pneumothorax and death.
4. **The flow of gas may be as a plurality of gentle streams flowing through the small fenestrations in the balloon cuff wall.** Thus, avoiding the risk of sheer-force injury induced by aiming a powerful jet of gas into the airways.
5. **Simplicity of design and production.** Producing a single-lumen tube is much less complicated and less expensive than a tube with a secondary channel embedded in its wall.
6. **The use of compressed gas facilitates a much smaller gas delivery system,** which is less expensive, more resilient and easier to use, store and transport.

Disclosure of Additional Features

This invention further discloses embodiments and features that may be used individually, or in combinations together with the basic configuration described in the above:

1. **Applying suction (negative pressure, vacuum) to the tube's inlet during the exhalation phase. This feature has the advantage of inducing a quicker and more complete deflation of the balloon cuff.**

2. Adding a pressure-sensing element at the distal tip of the tube to sense the intra-airway pressure throughout the ventilation. This pressure sensing element may be a pressure transducer (e.g. such as the Milar[®] catheter-tip transducer), or by passing a narrow pressure-sensing catheter through the length of the tube with a forward directed opening. The information on the intra-airway pressure may be monitored continuously. The information on the pressure at any time during the ventilation may be used to prevent excessive intra-airway pressure build-up, beyond a pre-set value, such as 30 cm H₂O. The information about the pressure may also be used to determine and control the desired peak inspiratory pressure (PIP) during each breath and the a desired positive end expiratory pressure (PEEP) (Figure 1b).
3. The flow (volume, pressure) pulse delivery apparatus may be constructed from programmable pneumatic elements and valves (e.g. from Bakara[®] Inc.), or from electronic elements without or with a micro computer and solenoid valves, or from any combination thereof as long as the apparatus can at least deliver pulses of flow at a specified flow rate, a specified pulse duration, and a specified number of pulses per minute. In one preferred embodiment, the flow pulse delivery apparatus also can respond to information on airway pressure so as to stop (abort) a pulse if a pre-determined maximal allowable intra-airway pressure (PIP) was exceeded. In addition, it may respond by starting or increasing a counter-flow if, during the expiratory phase, the intra-airway pressure has diminished under a pre-determined level of PEEP.
4. The shape of the balloon cuff. The balloon may have a trapezoid shape (Figure 3a), a cylindrical shape, i.e. essentially uniform circumference throughout its length (Figure 3b). The balloon also may have a shape that is designed to fit locally to the inner surfaces of the airways, while maximizing the area of the balloon cuff facing the airways and lung interior to allow for a large number of fenestrations (Figure 3c). Such shapes include a short bulging cuff, a non-uniform circumference cuff that has a narrow band at its mid point, a distally tapered balloon, a proximally tapered balloon (not shown), or a combination thereof. The balloons may be of different sizes (circumference and length) to best fit the

airways of certain individuals. Balloons of various shapes are produced by using special forms, or by incorporating a fine mesh of non-stretchable fibers at the desired shape in the balloon's wall material.

5. We further disclose a combination of gas emergence ports: through the balloon cuff wall fenestration and through an opening at the tip of the tube (Figure 4).
6. Additionally we disclose a method to prevent insertion of the tube too far into the airways, thereby avoiding the risk of wedging the tube in an airway. This is achieved by equipping the tip of the tube with a hinged ring of a diameter matching the narrowest airway in which the tip of tube may be lodged (Figure 5a). The ring prevents the catheter from being advanced too far into the lung. The ring may be made from a rigid material such as bio-compatible metal or plastics. Alternatively, the ring may be made from an inflatable narrow tube connected via a secondary channel to an external inflating device such as a syringe. Alternatively, the element for preventing wedging of the tube may be a spring or coiled element such as a spiral (Figure 5b) that is concealed by a retractable thin-wall sleeve during the insertion of the tube into the trachea. Once inside the trachea, the sheet may be retracted by pulling it mouthward, allowing the pre-stressed coiled element to spring out and attain its unstressed shape and dimensions inside the airways (Figure 5c). It is noted that the same elements may be useful to stabilize the tip of the tube and keep it about the center of the airway.
7. Yet another feature and detail of the new intra-airway ventilation method is a proximal side-port with an appropriate connector such as a Luer lock with a one-way valve that allows injection of liquids or gases into the gas stream flowing into the patient's airways (Figure 6). These liquids may contain medications, such as adrenaline, atropine and other therapeutic agents.
8. Another unique feature of the new intra-tracheal ventilator is a method for inserting a second catheter along-side the main catheter. Such secondary catheter or probe may be used to extract secretions from the airways by suction, lavage the lung, insert medications, observe the airways via a fiber-optic scope or a

miniature video camera, or to obtain samples of the airway tissue and lining by brushing or with a biopsy tool. Unlike with conventional endotracheal tubes, it is not possible to pass such catheters and probes through the lumen of the new tube. Therefore, we disclose means for directing the secondary catheter alongside the main intra-tracheal ventilation tube. This is achieved by surrounding the main tube by a sliding ring, preferably with a tapered (conical) profile (Figure 7). This ring is constructed with an inner diameter that is slightly larger than the outer diameter of the main tube and from a material that has minimum friction coefficient such as Teflon and therefore can move freely along the main catheter. Permanently attached to the ring is a holder, preferably constructed as a second ring through which the second catheter may be inserted. The second ring is also preferably tapered. The taper of the outer surface of both rings is needed in order to facilitate their easy passage through the vocal cords. The second ring is constructed with a latching mechanism such as an internal transverse groove and the secondary catheter is constructed with a matching protrusion that fits into the groove. To insert, the secondary catheter is inserted into the second ring with the protrusion locked in the transverse groove. During the insertion, the ventilation is stopped momentarily to prevent blocking the advancement of the secondary catheter by the inflating balloon. However, once the tip of the secondary catheter of probe has been advanced beyond the balloon, ventilation may be resumed. The catheter is then pushed inward into the airways with the first ring sliding along the main catheter. Once the rings and the tip of the secondary catheter have reached beyond the glottis and the vocal cords, and are positioned just above (proximal to) the inflatable balloon, its further advancement is blocked by a stopper protrusion built onto the external wall of the main tube. The user then turns or twists the secondary catheter to release the latching protrusion from the transverse groove, thereby allowing further advancement of the catheter into the lung. The distance of insertion may also be limited by positioning a tight ring around the secondary catheter, which limits how far it can be pushed into the airways. When the secondary catheter is pulled out, its protrusion pushes the sliding ring back outwards along the main catheter so that it is ready for further future use.

9. Under certain circumstances it is important to selectively ventilate different lung regions. This is particularly desirable when the lung disease is highly non-homogenous. The new intra-airway ventilation method may be used for such application. This is achieved by inserting a plurality of intra-airway ventilation tubes selectively into main-stem or lobar bronchi. These tubes are narrower and have smaller balloons than the intra-tracheal ventilation tubes, but are otherwise similar in construction and function. The tubes may be positioned using a fiber-optic or video camera scope that can be maneuvered to specific sites in the airways. The scope is used to place a guide wire in the desired pathway and the wire with a sliding ring, as disclosed in the previous section, guides the tube. A separate and independent flow-pulse delivery apparatus may activate each of the plurality of ventilation tubes. A rack of plurality of such apparatuses is disclosed herewith with a synchronized or independent flow-pulse delivery mechanisms. The delivered pulses may be in-phase with each other, or completely out-of-phase so that while some lung regions expand, others contract. Additionally, certain lung regions may be inflated to higher pressures while others are kept at low inflation pressure. It is further disclosed that one or more intra-airway ventilation catheters may be passed through an ordinary endotracheal tube for combined selective and global ventilation of the lung. An adapter is hereby disclose to allow passing a single or a plurality of intra-airway ventilation tubes through the lumen of a conventional endotracheal tube.

10. Additionally disclosed are meters, indicators and alarms that sense, indicate and verify the essential ventilation and gas exchange parameters in combination with the intra-tracheal and/or intra-airway ventilation method. These meters include: (1) the pressure of the inflow source, (2) The volume of each flow pulse, (3) the airway pressure, (4) the flow-pulse duration, and (5) the number of flow-pulses per minute.

11. If a pressure-sensing element is incorporated at the tip of the intra-airway or intra-tracheal ventilation tube, the pressure sensor may be used to detect the very instance of reduced intra-airway pressure caused by the patient's own

inspiratory effort. When such suddenly reduced pressure exceeds a certain pre-determined threshold it is sensed and delivery of a flow pulse is triggered.

Brief Description of the Figures

Figure 1a shows a block diagram of the basic intra-airway ventilation method.

Figure 1b shows a block diagram of the intra-airway ventilation method with a pressure-sensing element.

Figure 2a shows the intra-airway ventilation tube inside an airway during inspiration

Figure 2b shows the intra-airway ventilation tube inside an airway during expiration

Figure 3a shows the intra-airway ventilation tube with a trapezoid balloon cuff.

Figure 3b shows the intra-airway ventilation tube with a cylindrical balloon cuff.

Figure 3c shows the intra-airway ventilation tube with three additional shapes of the balloon cuff.

Figure 4 shows a tube with combined balloon cuff fenestration and a catheter-tip opening

Figure 5a shows a hinged ring tube-tip stabilizer

Figure 5b shows a coiled spiral tube-tip stabilizer before insertion without and with a retaining sleeve and the spiral after the retaining sleeve has been retracted.

Figure 6 shows the proximal side-port for injection of medications into the gas stream.

Figure 7a shows the sliding mechanism for insertion of a secondary catheter

Figure 7b shows a side view of the sliding mechanism and the primary and secondary catheters.

Detailed description of the figures

The block diagram of the basic intra-airway ventilation method is shown in Figure 1a. Each breath starts with the onset of a gas delivery pulse. The flow delivered into the tube enters the cuff through holes in the wall between the lumen of the tube and the

surrounding cuff (106 in Figure 2a). This flow inflates the balloon cuff sufficiently to occlude completely the airway in which it resides. For the duration of the pulse, additional gas flows into the cuff and then out of the cuff through multiple small fenestrations in the cuff wall facing the internal aspect of the lung. The flow continues for as long as the pulse duration (as set by the operator), or until a sufficient volume has been delivered (also as set by the operator). When either the desired duration, or volume have been reached, the flow pulse stops. This causes an immediate recoil and collapse of the balloon cuff, clearing the space between the tube and the airway wall, so that exhalation may start. The exhalation phase continues the duration set by the operator. Setting the inspiratory and expiratory times also determine the total respiratory rate of the patient. At the end of expiration duration, the system loops back to the inspiratory mode for the next inspiratory flow pulse.

Figure 1b shows the intra-airway ventilation method when operated with a pressure-sensing element. Each inspiratory phase starts with delivery of a flow pulse, which inflates the balloon cuff as outlined before. The inflation pulse continues for as long as determined by the operator or until a pre-specified volume has been delivered, unless the pressure inside the airways, sensed by the pressure-sensing element, has reached or exceeded the maximal peak inspiratory pressure (PIP). If PIP is reached, the flow pulse is aborted prior to the pre-determined end of the inspiration. Either ways, as soon as the flow pulse stops, the balloon cuff deflates to allow exhalation between the tube's external wall and airway's internal wall. Exhalation continues until the intra-airway pressure reaches or falls below the desired level of Positive End Expiratory Pressure (PEEP). When this pressure is sensed by the pressure-sensing element, the flow delivery system is activated to provide a PEEP counter-flow that partially inflates the balloon cuff and creates a balance between the in-flowing delivered gas and the exhalation flow. This process continues until the duration of exhalation has expired and a new inspiration cycle is started.

Figure 2 shows the intra-airway ventilation tube during operation. Figure 2a shows the tube 102 during inhalation. The tube is placed inside an airway 100. The in-flowing air penetrates the balloon cuff 104 through holes 106 in the tube's wall. The flow of air inflates the balloon cuff so that it completely occludes the airway, preventing air from

leaking out between the cuff and the airway internal surface. The air exits the balloon cuff through a plurality of small holes 108 in the wall of the balloon cuff that faces the inside of the lung. The total resistance of the cuff holes 108 is sufficiently larger than the total resistance of the tube wall holes 106, so that the balloon cuff remains inflated for as long as flow is maintained through the tube. The gas leaving the balloon cuff through the holes 108 inflates the lung to effect alveolar gas exchange.

Figure 2b shows the tube 102 inside an airway 100 during exhalation. Stopping the flow of gas removes the internal pressure inside the balloon cuff 104 that immediately collapses. Exhaled gas 110 then flows freely in the space between the tube and the internal airway surface. This flow is actuated by the higher than atmospheric alveolar pressure that was built up during the preceding inspiration.

Figure 3 shows several alternative shapes to the balloon cuff. Figure 3a shows a trapezoid balloon cuff shape. Figure 3b shows a cylindrical balloon cuff shape. Figure 3c shows a peaked balloon shape (top), a heart shaped balloon (middle), and a concave balloon (bottom). The various shapes are intended for best fitting the internal curvature of the airway surface and to maximize the surface area through which gas can exit from the balloon into the lung airways.

Figure 4 shows a tube that is perforated in its tip to facilitate additional air flow into the lung. The gas is blown into the lung through the hole in the tip of the tube 102 as well as through the fenestrations in the balloon's wall 114. A variant of this design is hereby disclosed wherein the gas is blown into the lung exclusively through a single hole or a plurality of holes at the tip of the tube and not through the balloon wall fenestrations.

Figure 5 shows means to stabilize the intra-airway ventilation catheter, to prevent it from slipping too deep into the lung and to center it about the middle of the airway. Figure 5a shows a hinged ring stabilizer. The ring 120 is attached to the tip of the tube by a cross bar 122 that can rotate around its axis thereby allowing rotating motion of the ring. The ring diameter is set to be large enough to prevent the tip of the tube from entering the next generation of airways (e.g. from the tracheal to the right main stem bronchus), thereby avoiding inadvertent "one lung" intubation. Figure 5b shows another method for achieving the purpose of limiting the tube's motion inside the airways. During the

insertion process, a cylindrical sleeve 124 covers and conceals the tube, the balloon cuff, and a wrapped around semi-rigid elastic coil spiral 126. Once the tube is in the desired position, the sleeve is retracted by pulling its proximal end outward, and the balloon cuff as well as the coiled spiral are exposed. The spiral 128 then springs out to its unstressed shape as shown in Figure 5c.

Figure 6 shows the proximal connector 142 of the tube to the gas-flow pulsating device ("ventilator"). Built into this connector is a port 144 for injection of liquid medications into the airways. The port is typically of the Luer Lock type that allows easy attachment of standard syringes. The port 144 is also typically equipped with a one-way valve mechanism 140 that prevent leak of gas from the tube through the port.

Figure 7 shows the means for sliding an accessory channel such as a suction catheter, or a fiber-optic bronchoscope into the airways alongside the intra-airway ventilation tube. Figure 7a shows a figure 8-tapered element 150 that is used to guide the secondary channel along the ventilation tube. The element has two cylindrical passages: one passage 152 is for the ventilation tube and the second passage 154 is for the accessory channel. Figure 7b shows a side view of the sliding element 150. It is shown riding on the ventilation tube with its balloon 104. The accessory channel 160 is shown inserted into its passage in the sliding element. A side protrusion 164 in the external wall of the accessory is inserted through groove 162 inside the sliding element and is anchored in the horizontal part of the groove so that when it is pushed inward the sliding element is pushed inward together with the sliding element. The secondary channel and the sliding element move inward along the primary ventilation catheter until its motion is blocked by the circumferential protrusion 166 just proximal to the balloon cuff where its motion is stopped. When the operator feels this block, he/she twists the secondary channel to release the protrusion 164 from the groove 162, thereby facilitating its further motion into the airways. During the insertion the balloon cuff 104 should remain deflated.

What is claimed as new is:

1. A method for intermittently inflating and deflating an elastic hollow cavity or organ through a connecting passage by inserting a cuffed tube into the passage; whereas the organ may be a lung of a person or an animal and; whereas the

passage may be the trachea or an airway of said lung and; whereas the cuff inflates and occludes the passage during the inflation phase by delivery of pressurized gas into the cuff through the tube and; whereas the cuff collapses during the deflation phase when the flow of pressurized gas into the cuff stops whereby allowing gas to exit from the elastic cavity or organ through the space formed between the collapsed cuff and the inner surface of the gas passage.

2. A cuffed tube wherein the elastic cuff inflates through holes connecting between the hollow lumen of the tube and the space inside the cuff and; whereas the elastic cuff deflates through the same holes back into the tube or through a plurality of small fenestrations in the outer cuff wall.
3. A pressure-sensitive element at or near the tip of the cuffed tube with means to transmit the pressure information from the tip of the tube to its proximal end.
4. A sliding double ring element that guides a secondary channel through the gas passage into the interior of the organ in parallel with and alongside the primary tube.
5. A method for stabilizing, centering and anchoring the tip of the tube in the desired location inside the gas passage.

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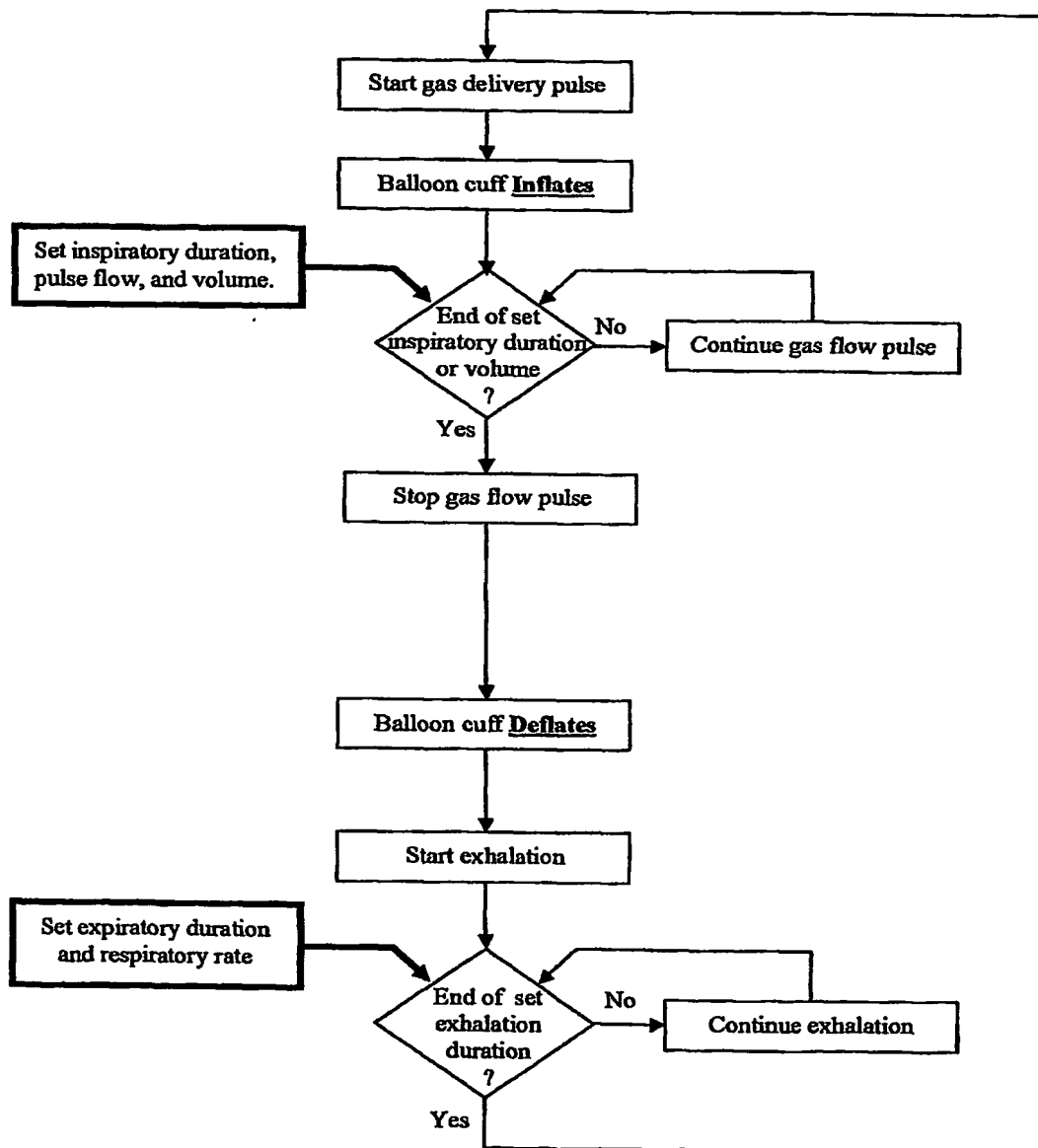


Figure 1b Block diagram of the intra-airway ventilation method with a pressure-sensing element

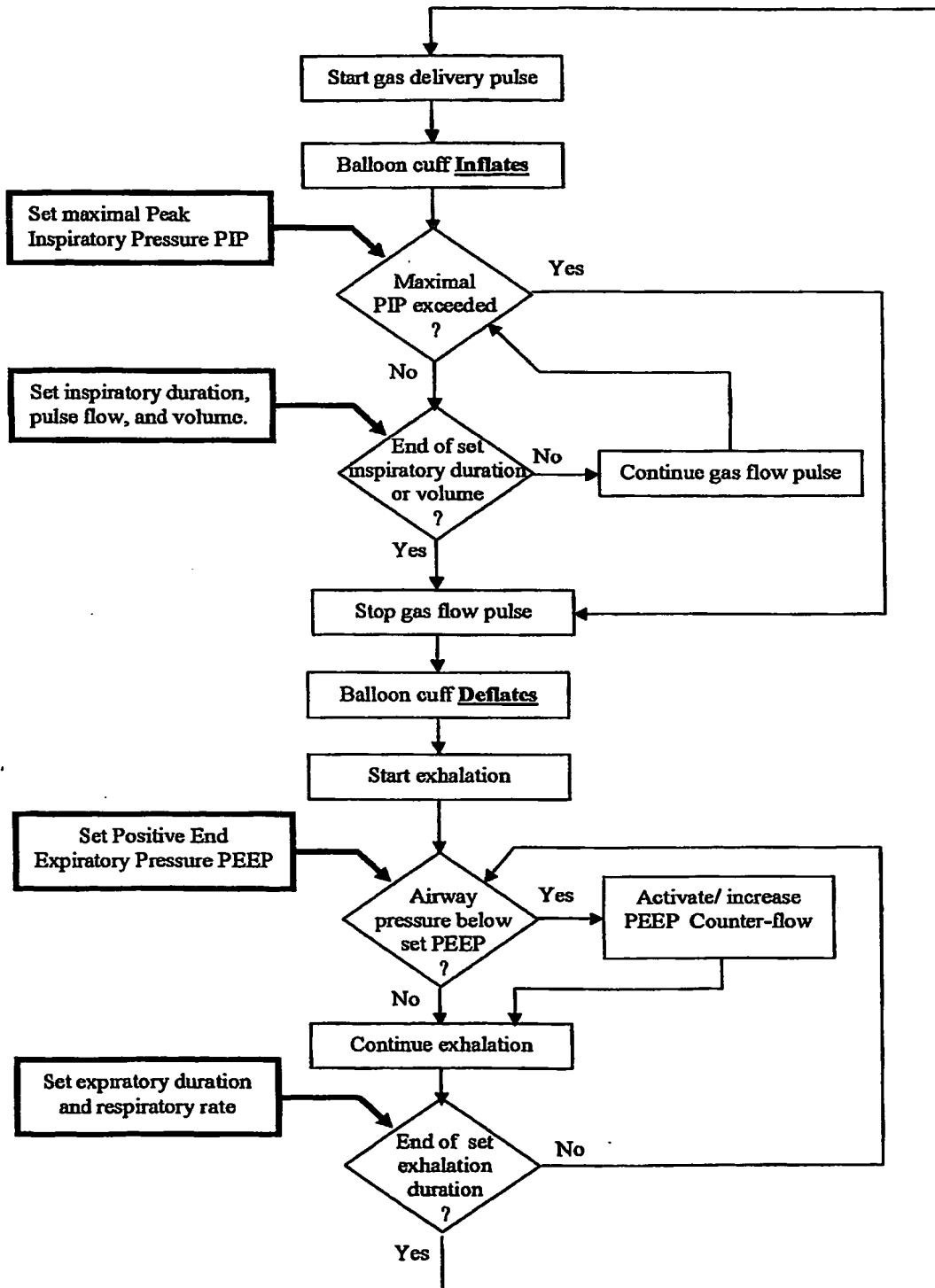


Figure 2a
Inspiration

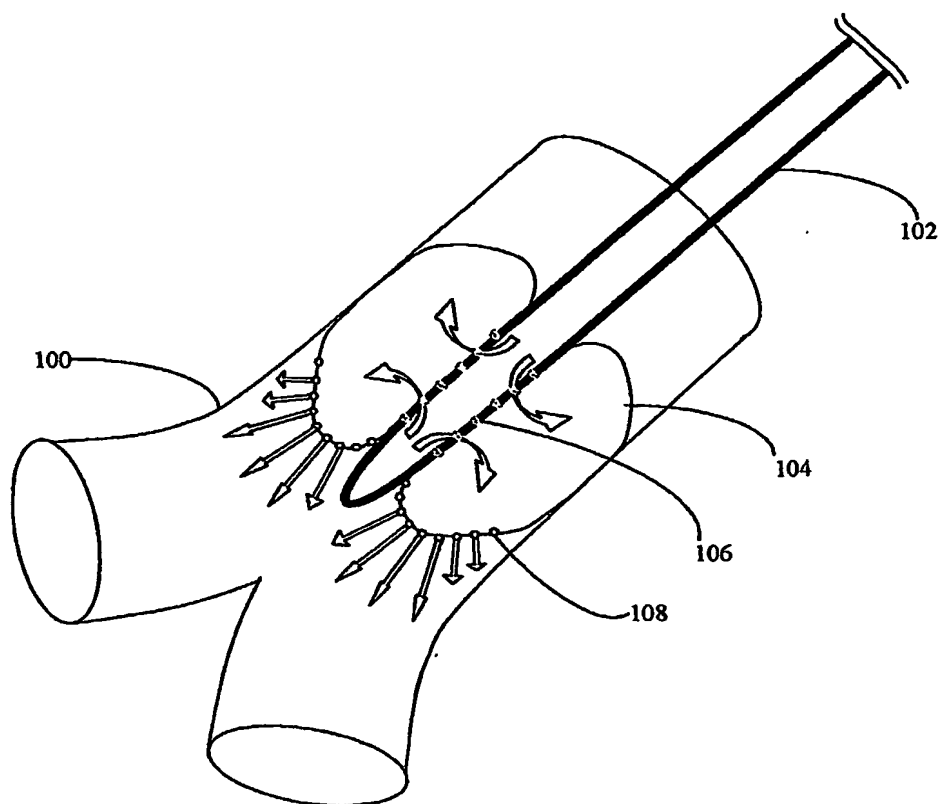


Figure 2b
Expiration

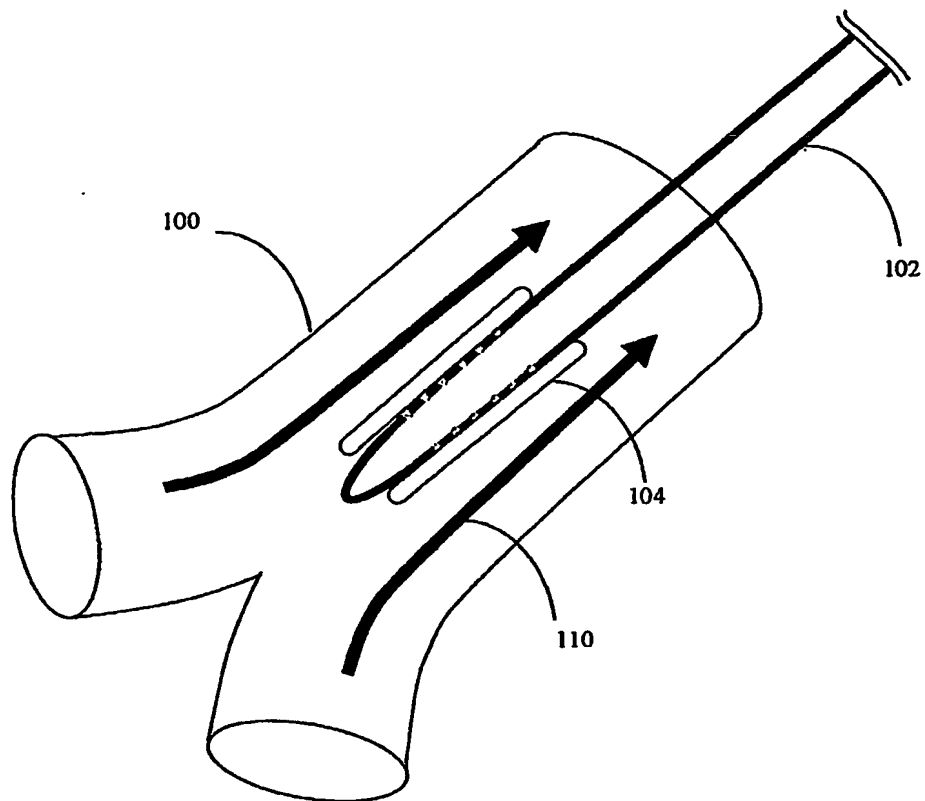


Figure 3a
Trapezoid balloon cuff

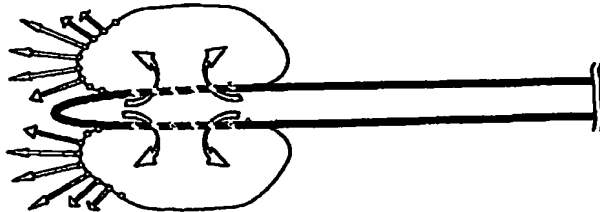


Figure 3b
Cylindrical balloon cuff

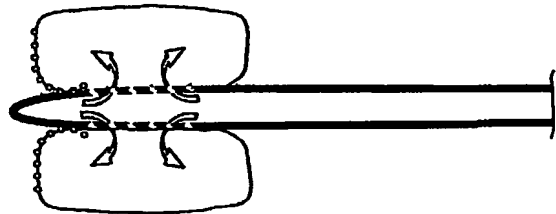


Figure 3c
Other balloon cuffs shapes

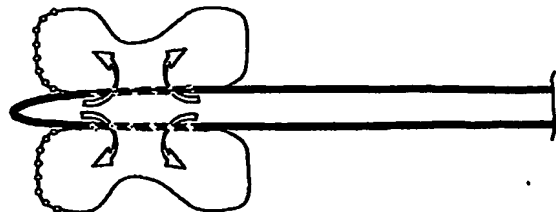
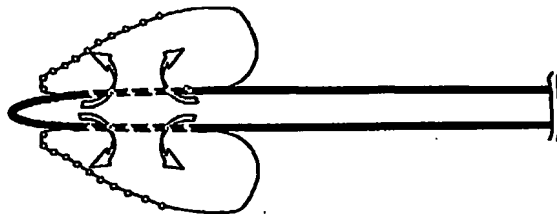
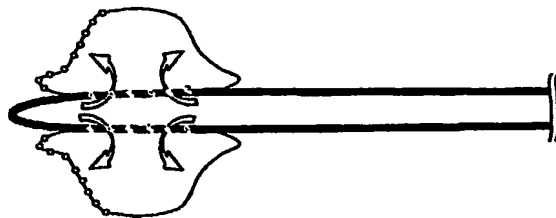
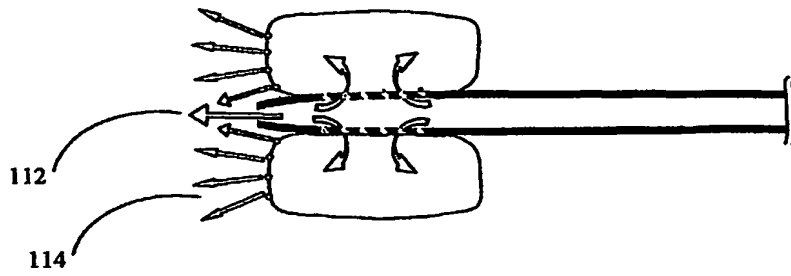


Figure 4
Tube with combined balloon cuff fenestrations and a catheter-tip opening.



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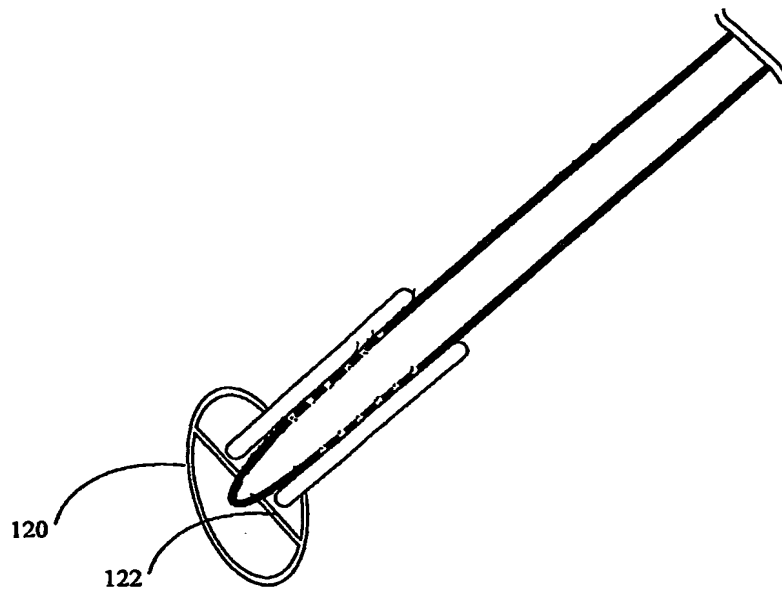


Figure 5b
Coiled spiral tube-tip stabilizer (pre-insertion) without (right) and with (left) retaining sleeve.

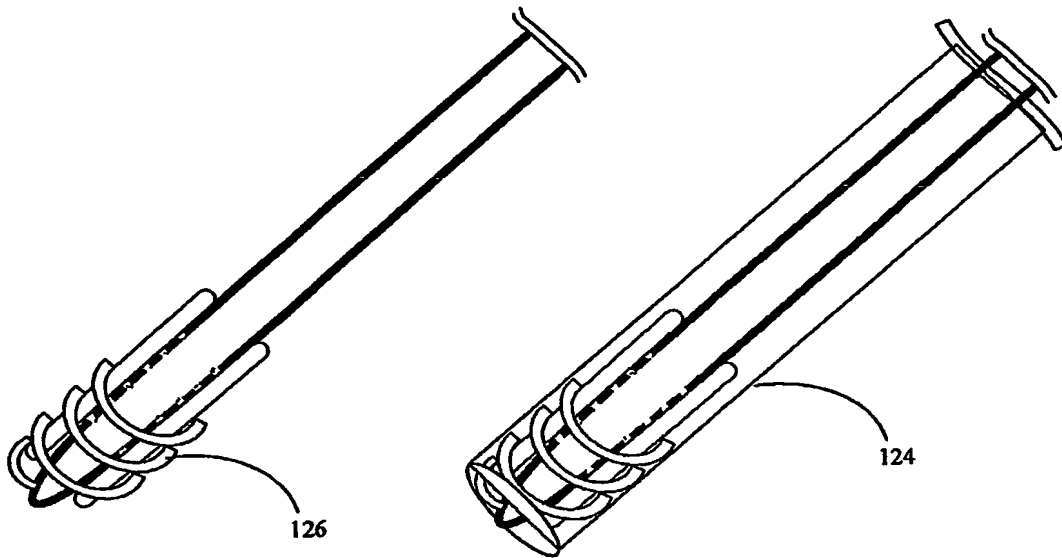


Figure 5c
Unstressed spiral tube-tip stabilizer (post-insertion)

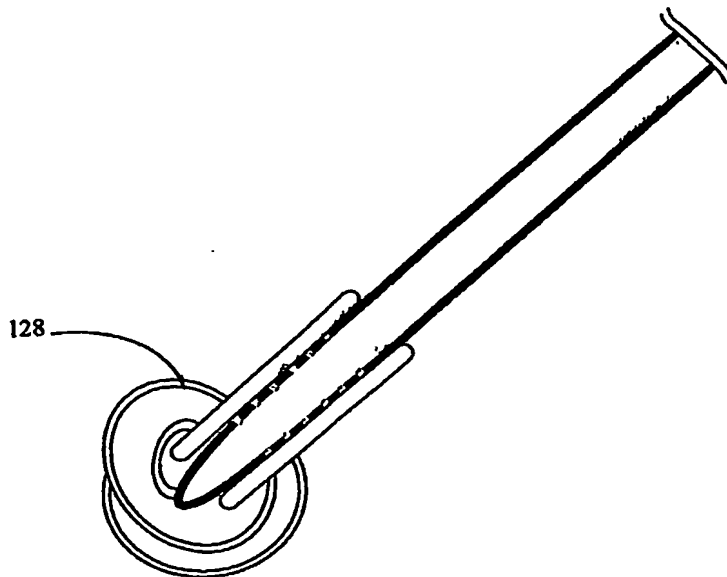


Figure 6
Proximal side-port for injection of medications into the gas stream.

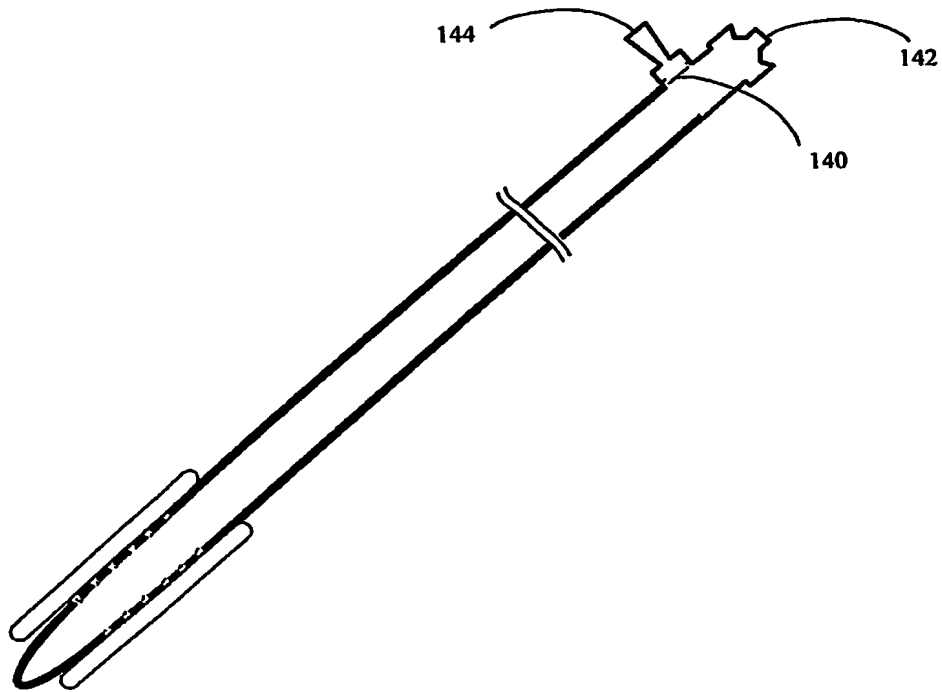


Figure 7a
Sliding mechanism for insertion of a secondary catheter.

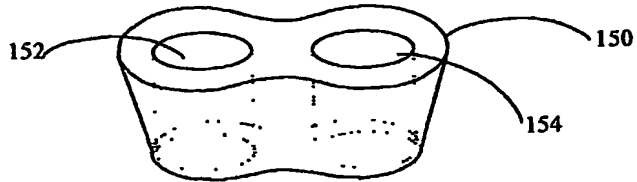


Figure 7b
Side view of the sliding mechanism.

